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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DONALD ROLLAND, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. REWALK ROBOTICS LTD., LARRY JASINSKI, AMI KRAFT, AMIT GOFFER, JEFF DYKAN, HADAR RON, ASAF SHINAR, WAYNE B. WEISMAN, YASUSHI ICHIKI, ARYEH DAN, GLENN MUIR, JOHN WILLIAM PODUSKA, DEBORAH DISANZO, BARCLAYS CAPITAL, INC., JEFFERIES LLC, CANACCORD GENUITY INC., SCP VITALIFE PARTNERS, YASKAWA ELECTRIC CORPORATION, ISRAEL HEALTHCARE VENTURES 2 L.P., PONTIFAX Defendants.	Case No: 3:17-cv-362 **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **Demand for Jury Trial** Complaint Filed: January 24, 2017

Plaintiff ("Plaintiff") by his attorneys, individually and on behalf of all others similarly situated, alleges the following based upon the investigation of Plaintiff's counsel, not including allegations specifically pertaining to Plaintiff's own knowledge. Counsel investigated, among other things: (1) a review of ReWalk Robotics LTD.'s ("ReWalk" or the "Company") public filings with the United States Securities and Exchange Commission ("SEC"); (2) press releases issued by ReWalk; (3) public conference calls, investor conferences, media and news reports about ReWalk; (4) public filings in several class actions[1] against the Company and certain of its directors and/or executive officers for violations of federal securities laws; and (5) other publically available information relating to the price and trading volume of ReWalk's ordinary shares. Plaintiff believes that after a reasonable time for discovery, additional evidentiary support will exist for the allegations set forth herein.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than defendants who purchased or otherwise acquired ReWalk securities pursuant and/or traceable to ReWalk's false and misleading Registration Statement and Prospectus (defined below) issued in connection with the Company's initial public offering on or about September 12, 2014 (the "IPO") seeking to recover compensable damages caused by defendants' violations of the Securities Act of 1933 (the "Securities Act").

2. ReWalk is a medical device company that designs, develops, and commercializes robotic exoskeletons for wheelchair-bound individuals and those with spinal cord injuries who need assistance walking. The robotic exoskeleton is worn by the user to help improve mobility. The Company markets and sells its products directly to institutions and individuals, as well as through third-party distributors. Formerly known as Argo Medical Technologies Ltd. ("Argo"), ReWalk is an Israeli corporation and was founded in 2001. ReWalk has numerous training centers throughout California, including locations in Pomona, Northridge, Long Beach, San Diego, Brea, Sacramento, Palo Alto and Englewood.

[1] Includes the following class actions all filed in the Superior Court of California, County of San Mateo: *Jackie888, Inc. v. ReWalk Robotics LTD., et al.*, Case No. 16-CIV-01454; *Paul Sislin v. ReWalk Robotics LTD., et al.*, Case No. 16-CIV-02212; *David Hershlikovitz v. ReWalk Robotics LTD., et al.*, Case No. 16-CIV-02213; and *Narbeh Nathan v. ReWalk Robitics LTD., et al.*, Case No. 16-CIV-02345.

3. ReWalk filed its draft registration statement with the SEC on May 16, 2014, which was subsequently amended several times, with the last amended registration statement filed on August 26, 2014. The SEC declared the registration statement effective on September 11, 2014 (the "Registration Statement") and on September 15, 2014, the Company filed its prospectus in connection with the IPO (the "Prospectus," together with the Registration Statement, the "Offering Documents").

4. In the IPO, the Company sold 3,450,000 ordinary shares (including an option provided to the underwriters of the IPO to purchase 450,000 ordinary shares) at a price of $12.00 per share for total proceeds of approximately $41.1 million. The total expenses of the IPO, including underwriting discounts and commissions were approximately $5.1 million and the Company's net proceeds from the IPO were approximately $36.3 million.

5. The Offering Documents contained information concerning the Company's two products offered at that time: ReWalk Personal and ReWalk Rehabilitation. The ReWalk Personal is designed for everyday use by individuals and is custom-fit for each user. The ReWalk Rehabilitation is designed for the clinical rehabilitation environment for exercise and therapy.

6. The Offering Documents contained information concerning government regulation of ReWalk's products by the United States Food and Drug Administration ("FDA"), the European Union and the Ministry of Health in Israel, among others. In particular, ReWalk was required to comply with certain extensive post-market regulatory requirements set forth by the FDA in a list of "special controls" for the Company to be able to market and sell its products.

7. The Offering Documents contain materially misleading statements and/or omit material information concerning the development and commercialization of the ReWalk Personal, including that defendants were aware that ReWalk would be unable to comply with the applicable "special controls" requirements or to provide the FDA with a post-market surveillance study as required by the Company to maintain ongoing sales of its products.

8. On September 30, 2015, the Company received a warning letter from the FDA regarding ReWalk's failure to conduct an adequate post-market surveillance plan following the FDA's initial clearance in June 2014, which described in detail the deficiencies that ReWalk was required to fix. However, the Company did not disclose this information until nearly five months later.

9. On or about February 25, 2016, the investing public learned the truth that ReWalk had been unable to comply with the FDA's postmarket surveillance requirements and "special controls," which information had not been disclosed in the Offering Documents. After the truth was revealed, ReWalk's ordinary share price plummeted, harming investors.

10. As a result of defendants' materially misleading statements and omissions described herein, ReWalk securities traded at artificially inflated prices. However, after disclosure of defendants' materially misleading statements and omissions, ReWalk's ordinary share price suffered a precipitous decline in market value, thereby causing significant losses and damages to Plaintiff and the Company's shareholders who purchased ReWalk ordinary shares pursuant to and/or traceable to the IPO.

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v).

13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) as ReWalk conducts substantial business in this District and defendants have received substantial compensation in this District.

14. In connection with the acts, conduct and other wrongs alleged herein, defendants either directly or indirectly used the means and instrumentalities of interstate commerce, including but not limited to the United States mails, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

15. Plaintiff acquired the ordinary shares of ReWalk pursuant and/or traceable to the Company's IPO and has been damaged thereby.

16. Defendant ReWalk is an Israeli corporation with approximately ten Training Centers throughout California, including one located at 3801 Miranda Avenue, Palo Alto, California 94303.

The Company's ordinary shares trade on the NASDAQ Global Market under the ticker symbol "RWLK."

The Individual Defendants

17. Defendant Larry Jasinski ("Jasinski") has been the Chief Executive Officer ("CEO") and a member of the Board since February 2012. Defendant Jasinski was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

18. Defendant Ami Kraft ("Kraft") has been the President of the Company since August 2016 and was the Chief Financial Officer ("CFO") of ReWalk from January 2009 through the IPO. Defendant Kraft was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

19. Defendant Amit Goffer ("Goffer") founded ReWalk and was the President, Chief Technical Officer and a member of the Board at the time of the IPO. Defendant Goffer was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement. Defendant Goffer ceased serving as the Company's President and Chief Technology Officer on November 18, 2015 and as a member of the Board of December 3, 2015.

20. Defendant Jeff Dykan ("Dykan") has been a member of the Board since 2006 and the Chairman of the Board since 2009. Defendant Dykan was appointed to the Board by significant shareholder SCP Vitalife, in which defendant Dykan has been a director of SCP Vitalife GP, the corporate general partner of the common general partner of each of SCP Vitalife Partners II L.P. and its successor fund, SCP Vitalife Partners (Israel) II L.P., since 2002 and 2007, respectively. Defendant Dykan was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

21. Defendant Hadar Ron ("Ron") was a member of the Board from 2011 until her resignation on April 30, 2015. Defendant Ron was appointed by significant shareholder Israel HealthCare Ventures, in which defendant Ron has been the Managing Partner of Israel HealthCare Ventures, an Israeli venture capital fund, since March 2001. Defendant Ron was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

22. Defendant Asaf Shinar ("Shinar") was a member of the Board from 2011 until his resignation on February 23, 2015. Defendant Shinar was appointed to the Board by significant shareholder Pontifax, in which defendant Shinar has been the CFO of Pontifax Group, an Israeli venture capital fund, since 2007. Defendant Shinar was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

23. Defendant Wayne B. Weisman ("Weisman") has been a member of the Board since 2009. Defendant Weisman was appointed to the Board by significant shareholder SCP Vitalife Partners II L.P., in which defendant Weisman has been a director of SCP Vitalife GP, since 2007. Defendant Weisman has also been the managing member of SCP Vitalife Management Company, LLC, which provides management services to the common general partner of SCP Vitalife. Defendant Weisman was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

24. Defendant Yasushi Ichiki ("Ichiki") has been a member of the Board since 2014. Defendant Ichiki was appointed to the Board by significant shareholder Yaskawa Electric Corporation, in which defendant Ichiki has been the Manager of the Corporate Planning Group, Corporate Planning Division, of Yaskawa Electric Corporation since May 2014. Defendant Ichiki was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

25. Defendant Aryeh Dan ("Dan") has been a member of the Board since 2013 and was appointed by significant shareholder Yaskawa Electric Corporation, in which defendant Dan has been the President and CEO of Yaskawa Europe Technology since 2005. Defendant Dan was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

26. Defendant Glenn Muir ("Muir") has been a member of the Board since 2014. Defendant Muir was involved in preparing the Offering Documents and signed or authorized the signing of the Registration Statement.

27. Defendants Jasinski, Kraft, Goffer, Dykan, Ron, Shinar, Weisman, Ichiki, Dan and Muir are collectively referred to as the "Individual Defendants."

The Secondary Offering Defendants

28. Defendant John William Poduska ("Poduska") was a member of the Board at the time of the Secondary Offering (described below) and signed or authorized the signing of the Secondary Offering Registration Statement and Prospectus.

29. Defendant Deborah DiSanzo ("DiSanzo") was a member of the Board at the time of the Secondary Offering and signed or authorized the signing of the Secondary Offering Registration Statement and Prospectus.

30. Defendants Poduska and DiSanzo are referred to herein as the Secondary Offering Defendants.

The Underwriter Defendants

31. Defendant Barclays Capital, Inc. ("Barclays") is an investment banking and financial services corporation and acted as an underwriter for ReWalk's IPO, helping to draft and disseminate the Registration Statement and Prospectus and agreed to purchase 1,425,000 shares of ReWalk ordinary shares in the IPO.

32. Defendant Jefferies LLC ("Jefferies") is an investment banking and financial services corporation and acted as an underwriter for ReWalk's IPO, helping to draft and disseminate the Registration Statement and Prospectus and agreed to purchase 1,125,000 shares of ReWalk ordinary shares in the IPO.

33. Defendant Canaccord Genuity Inc. ("Canaccord") is an investment banking and financial services corporation and acted as an underwriter for ReWalk's IPO, helping to draft and disseminate the Registration Statement and Prospectus and agreed to purchase 450,000 shares of ReWalk ordinary shares in the IPO.

34. Defendants Barclays, Jefferies and Canaccord are collectively referred to as the "Underwriter Defendants."

35. Defendant ReWalk and the defendants who signed the Registration Statement and Prospectus are liable for the false and misleading statements incorporated into the Registration Statement and Prospectus. The Underwriter Defendants drafted and disseminated the Registration Statement and Prospectus and were paid an estimated $2,898,000 in connection therewith (upon full

exercise of the underwriters' option to purchase additional shares). The Underwriter Defendants' failure to conduct adequate due diligence investigations was a substantial factor leading to the harm complained of herein.

36. The Underwriter Defendants were responsible for the drafting and dissemination of the Registration Statement and Prospectus and failed to conduct a proper investigation that led to the damages caused by the allegations herein. The Underwriter Defendants are liable for the false and misleading Registration Statement and Prospectus.

37. The Underwriter Defendants are investment banking firms with specialization in underwriting initial public offerings and were the underwriters for ReWalk's IPO. Together they received approximately $2,898,000 in fees. The Underwriter Defendants all agreed that in return for their share of the ReWalk IPO proceeds, they would merchandize ReWalk ordinary shares in the IPO. As such, the Underwriter Defendants travelled to multiple cities with a ReWalk representative to meet with potential investors and presented favorable information regarding ReWalk.

The Venture Capital Defendants

38. Defendant SCP Vitalife Partners ("SCP Vitalife Partners") includes the following affiliated entities: SCP Vitalife Partners II, L.P. ("SCP Vitalife Partners II"), a limited partnership organized in the Cayman Islands; SCP Vitalife Partners (Israel) II, L.P. ("SCP Vitalife Partners Israel II"), a limited partnership organized in Israel; Vitalife Partners (Overseas) L.P. ("Vitalife Partners Overseas"); Vitalife Partners (Israel) L.P. ("Vitalife Partners Israel"); Vitalife Partners (D.C.M) L.P. ("Vitalife Partners DCM"); and SCP Vitalife II Associates, L.P. ("SCP Vitalife Associates"), a limited partnership organized in the Cayman Islands. SCP Vitalife Associates is the general partner of SCP Vitalife Partners II and SCP Vitalife Partners Israel II. SCP Vitalife II GP, Ltd. ("SCP Vitalife GP"), organized in the Cayman Islands, is the general partner of SCP Vitalife Associates. Defendants Dykan and Weisman are the directors of SCP Vitalife GP. Prior to the IPO, SCP Vitalife Partners and its affiliates beneficially owned 1,859,940 ordinary shares of ReWalk, or approximately 24.1%. After the IPO, SCP Vitalife Partners and its affiliates beneficially owned 1,953,984 ordinary shares of ReWalk, or approximately 17.1%.

39. Defendant Yaskawa Electric Corporation ("Yaskawa") is a Japanese corporation. Defendant Dan has been the President and CEO of Yaskawa Europe Technology, an affiliate of Yaskawa, since 2005 and was appointed to the Board by Yaskawa. Defendant Ichiki has been the Manager of the Corporate Planning Group, Corporate Planning Division of Yaskawa since May 2014 and was appointed to the Board by Yaskawa. Yaskawa beneficially owned 1,561,968 ordinary shares of ReWalk, or approximately 20.4%, before the IPO and approximately 13.7% of the Company after the IPO.

40. Defendant Israel Healthcare Ventures 2 L.P. ("IHCV") is a limited partnership incorporated under the laws of Island of Guernsey. IHCV2 General Partner Limited, a company incorporated under the laws of the Island of Guernsey, is the sole general partner of IHCV. Defendant Ron has been the Managing Partner of Israel HealthCare Ventures and was appointed to the Board Israel HealthCare Ventures, an Israeli venture capital fund. Prior to the IPO, IHCV beneficially owned 1,476,702 ordinary shares of ReWalk, or approximately 19.0%. After the IPO, IHCV beneficially owned 1,445,886 ordinary shares of ReWalk, or approximately 12.6%.

41. Defendant Pontifax ("Pontifax") includes the following affiliated entities: Pontifax (Cayman) II, L.P., Pontifax (Israel) II, L.P., and Pontifax (Israel) II–Individual Investors, L.P. Pontifax Management II L.P. ("Pontifax Management") is the general partner of the entities affiliated with Pontifax and Pontifax Management 2 G.P. (2007) Ltd. ("Pontifax Management GP") is the general partner of Pontifax Management. Defendant Shinar was appointed to the Board by Pontifax and has been the CFO of Pontifax Group, an Israeli venture capital fund, since 2007. Prior to the IPO, Pontifax and its affiliates beneficially owned 898,758 ordinary shares of ReWalk, or approximately 11.6%. After the IPO, Pontifax and its affiliates beneficially owned 950,314 ordinary shares of ReWalk, or approximately 8.3%.

42. Defendants SCP Vitalife Partners, Yaskawa, IHCV and Pontifax are collectively referred to herein as the "Venture Capital Defendants."

43. Upon the closing of the IPO, entities affiliated with the Venture Capital Defendants beneficially owned approximately 51.4% of ReWalk's outstanding ordinary shares.

44. Defendant ReWalk, the Individual Defendants, the Underwriter Defendants, the Secondary Offering Defendants and Venture Capital Defendants are collectively referred to herein as the "defendants."

SUBSTANTIVE ALLEGATIONS

Background of the Company and the De Novo Application

45. ReWalk – formerly called Argo Medical Technologies, Ltd. ("Argo")[2] – was founded by defendant Goffer in 2001 and designs, develops and commercializes exoskeletons to help wheelchair-bound individuals with mobility impairments or other medical conditions to be able to stand and walk. ReWalk currently offers two products: the ReWalk Personal (designed for everyday use by individuals) and the ReWalk Rehabilitation (designed for the clinical rehabilitation environment).

46. Immediately prior to the IPO, on June 26, 2014, the FDA approved the Company's *de novo* premarket approval application ("PMA"), recognizing the Company's product "*de novo*" status since there are no substantially equivalent medical devices on the market.[3]

47. Under the so called "direct de novo" application process, medical devices that demonstrate the potential to address unmet medical needs for irreversibly debilitating conditions are subject to PMAs or *de novo* requests through the FDA's "Expedited Access Pathway" ("EAP")[4] under sections 515(d) and 513 of the Food, Drug and Cosmetic Act of 1938 (the "FD&C Act"). Through the Expedited Access Pathway, premarket data requirements are significantly decreased (including safety

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[2] The Company changed its name from Argo Medical Technologies, Ltd. to ReWalk Robotics Ltd. sometime between June 13, 2014 and June 25, 2014. ReWalk maintains its registered agent in the United States as Argo Medical Technologies, Inc., a wholly-owned subsidiary of ReWalk.

[3] Letter from Jonette R. Foy, Deputy Director for Engineering and Science Review, Office of Device Evaluation, Center for Devices and Radiological Health to John Hamilton, Vice President Regulatory/Clinical, Argo Medical Technologies, Inc. (June 26, 2014), *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf13/DEN130034.pdf.

[4] Expedited Access For Premarket Approval And *De Novo* Medical Devices Intended For Unmet Medical Need for Life Threatening Or Irreversibly Debilitating Diseases Or Conditions: Guidance For Industry And Food And Drug Administration Staff, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, at 4-5 (Apr. 13, 2015), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf (the "April 13, 2015 FDA Guidance").

data, testing, and surveillance reporting data) in order to provide expedited access to new and unique medical devices for patients "willing to assume greater risk for earlier access to a medical device." April 13, 2015 FDA Guidance, at 5.

48. The June 26, 2014 letter from the FDA's Center for Devices and Radiological Health ("CDRH") set forth a summary of the CDRH's review of the ReWalk Personal, including a list of safety concerns and "special controls." The FD&C Act compensates for the expedited direct *de novo* review – and particularly safety surveillance data and testing requirements – by significantly "increasing post-market data, surveillance, and clinical testing requirements ***when appropriate***." April 13, 2015 FDA Guidance, at 5.

49. The FDA classifies medical device candidates for marketing approval according to the degree of difficulty in assuring their safety and effectiveness. Medical devices posing a high safety risk (designated as "class III" by the FDA) are not eligible for the Expedited Access Path direct *de novo* approval and must go through the FDA's full marketing approval process. Medical devices posing a low safety risk (designated as "class I" by the FDA), typically receive direct *de novo* approval with little if any post-market conditions since they are deemed to pose a low safety risk and therefore may achieve full marketing status by simply complying with general FDA controls concerning quality, facility registration, and reporting of adverse events and labeling concerns. However, because *de novo* medical devices with a class II safety classification are deemed to pose a serious (though be it not "high") safety risk, the FDA may require compliance not only with general controls, but also "special controls," which may be more or less detailed (and may include further clinical and non-clinical testing demonstrating a reasonable assurance of safety and effectiveness of the product).

50. The FDA designated the ReWalk Personal as a "class II" *de novo* medical device, *i.e.*, a unique medical device addressing an unmet need, posing a moderate safety risk, as detailed in the FDA's June 26, 2014 warning letter. The June 26, 2014 warning letter detailed multiple safety concerns, including at the top of the list, "Instability, Falls, and Associated Injuries," which could result in injury or death to the device user. Given the severity of the potential safety danger associated with the ReWalk Personal, in its June 26, 2014 letter, the FDA imposed extensive special controls

upon the Company, including extensive additional post-market requirements for data, safety surveillance, and clinical and non-clinical testing.

51. The FDA's June 26, 2014 letter detailed special controls requiring extensive successful post-market safety surveillance and clinical and non-clinical testing of the product, with failure to comply with the special controls potentially leading to removal of the product's premarket marketing authorization. According to the FDA, "[p]ostmarket surveillance is a collection of processes and activities the FDA uses to monitor the safety and effectiveness of medical devices once they are on the market. These activities are designed to generate information to quickly identify poorly performing devices and other safety problems, accurately characterize real-world device performance and clinical outcomes, and facilitate the development of new devices, or new uses for existing devices."[5]

52. The FDA's June 26, 2014 Letter identified nine categories of potential risks with associate mitigation measures each of which contained numerous subcategories of risks associated with the general risk category, nearly all of which provided for clinical testing as the first mitigation measure to be taken to prevent the associated risk from occurring. The list was extensive in its breadth of identified risks, necessary mitigation steps, and number of matters requiring attention and action by the Company, including the following:

[5] Device Postmarket Surveillance, U.S. Food & Drug Administration, *available at* http://www.fda.gov/MedicalDevices/Safety/CDRHPostmarketSurveillance/default.htm.

RISKS TO HEALTH

Table 14 below identifies the risks to health that may be associated with use of the Powered Exoskeleton devices and the measures necessary to mitigate these risks.

Identified Risk	Mitigation Measure
Instability, Falls, and Associated Injuries	Clinical Testing Trainin g Software Verification, Validation, and Hazard Analysis Wireless Testing Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI) Testing Electrical Safety Testing Design Characteristics Non-clinical Performance
Bruising, Skin Abrasion, Pressure Sores, Soft Tissue Injury	Clinical Testing Trainin
Diastolic hypertension and changes in blood pressure, and heart rate	Clinical Testing Trainin
Adverse Tissue Reaction	Biocompatibility Assessment
Premature Battery Failure	Battery Testin
Interference with Other Electrical Equipment/Devices	EMC/EM I testing
Burns, Electrical Shock	Electrical Safety testing Thermal testing
Device Malfunction resulting in Unanticipated Operation (e.g., Device Stoppage, Unintended Movement)	Clinical testing Non-clinical Performance Testing Training Software Verification, Validation, and Hazard Analysis Electrical Safety Testing Battery Testing Water/Particle Ingress Testing Wireless Testing EMC/EMI

Use Error	Clinical Testing Trainin

Table 2: Identified Risks to Health and Mitigation Measures

53. The FDA's June 26, 2014 Letter further listed numerous special controls that the Company would have to comply with, including:

- Elements of the device materials that may contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must validate electronic compatibility/interference (EMC/EMI), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.
- Appropriate software verification, validation, and hazard analysis must be performed.
- Design characteristics must ensure geometry and materials composition are consistent with intended use.
- Non-clinical performance must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:
  - Mechanical bench testing (including durability testing) to demonstrate that the device will withstand forces, conditions and environments encountered during use.
  - Simulated use testing (i.e. cyclic loading testing) to demonstrate performance of device commands and safeguard under worst case conditions and after durability testing.
  - Verification and validation of manual override controls are necessary, if present.
  - The accuracy of device features and safeguards.
  - Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance.
- Clinical testing must demonstrate safe and effective use and capture any adverse events observed during clinical use when used under the proposed conditions of use, which must include considerations for:
  - Level of supervision necessary
  - Environment of use (e.g., indoors and/or outdoors) including obstacles and terrain representative of the intended use environment
- A training program must be included with sufficient educational elements so that upon completion of training program, the clinician, user and companion can:
  - Identify the safe environments for device use
  - Use all safety features of device
  - Operate the device in simulated or actual use environments representative of indicated environments and use
- Labeling for the Physician and User must include the following:

- appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities and environments that may put the user at greater risk.
- specific instructions and the clinical training needed for the safe use of the device, which includes:
  - instructions on assembling the device in all available configurations,
  - instructions on fitting the patient,
  - instructions and explanations of all available programs and how to program the device,
  - instructions and explanation of all controls, input, and outputs,
  - instructions on all available modes or states of the device,
  - instructions on all safety features of the device, and
  - instructions for properly maintaining the device.
- information on the patient population for which the device has been demonstrated to have a reasonable assurance of safety and effectiveness.
- pertinent non-clinical testing information (e.g., EMC, battery longevity)
- a detailed summary of the clinical testing including:
  - Adverse events encountered under use conditions.
  - Summary of study outcomes and endpoints.
  - Information pertinent to use of the device including the conditions under which the device was studied [e.g., level of supervision or assistance, and environment of use (e.g., indoors and/or outdoors) including obstacles and terrain].

54. In light of all of the above, the FDA direct *de novo* approval of the ReWalk Personal medical device is more accurately described as receiving conditional marketing approval, than the final marketing approval issued by the FDA in the non-expedited approval process applicable to all but novel or *de novo* medical devices.

55. The FDA's direct *de novo* approval of the ReWalk Personal included a requirement for a post-market safety surveillance plan which called for the gathering, production, analysis and reporting of extensive information summarized in 24 CFR 822.10, effective in 2014, as follows:

§ 822.10 What must I include in my surveillance plan?

Your surveillance plan must include a discussion of:

(a) The plan objective(s) addressing the surveillance question(s) identified in our order;

(b) The subject of the study, e.g., patients, the device, animals;

(c) The variables and endpoints that will be used to answer the surveillance question, e.g., clinical parameters or outcomes;

(d) The surveillance approach or methodology to be used;

(e) Sample size and units of observation;

(f) The investigator agreement, if applicable;

(g) Sources of data, e.g., hospital records;

(h) The data collection plan and forms;

(i) The consent document, if applicable;

(j) Institutional Review Board information, if applicable;

(k) The patient follow up plan, if applicable;

(I) The procedures for monitoring conduct and progress of the surveillance;

(m) An estimate of the duration of surveillance;

(n) All data analyses and statistical tests planned;

(o) The content and timing of reports.

56. To be able to comply with the extensive requirements imposed by the FDA upon the Company to maintain continued marketing clearance for the ReWalk Personal – including production of compliant postmarket safety surveillance data – the Company would have required significant numbers of experienced regulatory compliance staff, which it did not employ as of June 26, 2014.

57. The Company's lack of resources to comply with the FDA's requirements or "special controls" set forth in the June 26, 2014 Letter, including postmarket surveillance study data, resulted in the Company's repeated failures to comply with FDA demands regarding the postmarket surveillance data during the following months.

58. On September 29, 2014, the FDA informed the Company that the Company's proposed postmarket surveillance plan lacked the basic required information which the FDA had demanded in the FDA's June 26, 2014 Letter. The FDA further informed the Company of the deficiencies in the Company's submission and required a complete response within 30 days.

59. On November 5, 2014, the FDA informed the Company that the Company had failed to timely respond to the FDA's September 29, 2014 letter and ReWalk then submitted a postmarket surveillance study plan proposal the next day, November 6, 2014.

60. In a letter dated February 13, 2015, the FDA informed ReWalk that the ReWalk's November 6, 2014 proposed postmarket surveillance study plan lacked the basic required information which the FDA had demanded in the June 26, 2014 Letter. Again, the FDA listed the deficiencies in the Company's second submission and required a complete response within 30 days.

61. On March 16, 2015, the FDA informed the Company via email that the Company had failed to timely respond to the FDA's February 13, 2015 letter and demanded a response. On March 20, 2015, the Company responded by email to the FDA and stated that a response would be submitted by April 15, 2015. However, the Company did not send a response to the FDA by April 15, 2015.

62. On April 16, 2015, the FDA informed the Company that the Company had failed to timely respond to the FDA's February 13, 2015 letter. On May 22, 2015, the Company replied that it was in a position to respond to all but one issue and asked to discuss that issue with the FDA staff before submitting the formal response.

63. From June 12, 2015 to July 28, 2015, the FDA attempted multiple times (by phone and email), without success, to coordinate the requested teleconference with ReWalk in an attempt to resolve the outstanding issues. On June 24, 2015, the FDA notified the Company via email that ReWalk's postmarket surveillance study did not comply with section 522 of the FD&C Act.

64. On August 10, 2015, the Company informed the FDA (for the first time) that it was proposing substantial changes to the postmarket surveillance study plan and requested an in-person meeting should the FDA have any questions regarding the major proposed changes. On September 2, 2015, after reviewing the proposed changes, the FDA provided feedback to the Company and recommended that the Company submit a revised postmarket surveillance study plan incorporating the FDA feedback and addressing the deficiencies identified in the FDA. Once again, the Company did not timely respond.

65. Finally, in the face of the Company's continued failure to produce a compliant postmarket surveillance study plan, on September 30, 2015, the FDA issued ReWalk a warning letter (the "Warning Letter") detailing ReWalk's failure to propose, let alone conduct, an adequate postmarket surveillance study plan following the FDA's initial clearance and demand for a postmarket surveillance study in June 2014.[6] The Warning Letter stated, in pertinent part:

[6] Letter from Jan B. Welch, Acting Director, Office of Compliance, Center for Devices and Radiological Health to John V. Hamilton, Vice President, Regulatory, Argo Medical Technologies, Inc. (Sept. 30, 2015), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm487328.htm.

The Food and Drug Administration (FDA) authorized marketing of the ReWalk device under a de novo classification (K131798/DEN130034) on June 26, 2014. On that same day, FDA ordered Argo Medical Technologies, Inc. (Argo) to conduct post-market surveillance of the ReWalk device, in accordance with section 522 of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 360l, and Title 21 of the Code of Federal Regulations (CFR) Part 822.

FDA issued this order (PS140001) (the "522 Order") because the device's failure to prevent a fall would be reasonably likely to cause serious user injury and/or death through fall related sequelae, such as traumatic brain injury (TBI), spinal cord injury (SCI), and fractures to the user. In addition, an individual assisting the user could also be placed at risk of harm from a potential fall.

Argo's proposed 522 post-market surveillance (PS) study plan synopsis was received by FDA on July 31, 2014. FDA reviewed the PS study plan synopsis and informed you in a letter dated September 29, 2014 that Argo's submission lacked the information needed to complete the review. FDA listed the deficiencies with your firm's submission and required a complete response within 30 days, but the Agency did not receive a response from your firm within 30 days.

On November 5, 2014, FDA notified you that your firm's response was overdue. FDA then received a letter from you dated November 6, 2014 enclosing a PS study plan (PS140001/A001). FDA reviewed the PS study plan and, in a letter dated February 13, 2015, informed you that Argo's submission dated November 6, 2014 also lacked the information needed to complete the review. FDA listed the deficiencies with your firm's submission and required a complete response within 30 days, but the Agency did not receive a response from your firm within 30 days.

On March 16, 2015, FDA notified you via email that Argo's response to FDA's February 13, 2015 letter was overdue and asked when your firm would provide its response. On March 20, 2015, you responded via email to FDA and stated that the response would be submitted by April 15, 2015. However, FDA did not receive a response by April 15, 2015.

On April 16, 2015, FDA again requested a status update on the overdue Argo response to FDA's February 13, 2015 letter. On May 22, 2015, Argo replied to FDA stating that it was in a position to respond on all but one issue and asked to discuss that issue with FDA staff before submitting the formal response. FDA attempted multiple times [via phone and email], from June 12, 2015 to July 28, 2015, to coordinate the requested teleconference with your firm in an attempt to resolve the outstanding issues. FDA also notified you in an email dated June 24, 2015 that the Agency considered Argo's 522 study to be out of compliance.

Argo did not reply to FDA's request for proposed teleconference dates until July 29, 2015. In your July 29, 2015 email, you stated that your firm would have proposed dates for the teleconference by the week of August 3, 2015. However, on August 10, 2015, Argo notified FDA for the first time that it was proposing substantial changes to the methods and study plan (PS140001/A001) and requested an in-person meeting with FDA if the Agency had any questions regarding these major proposed changes.

After reviewing the proposals in Argo's August 10, 2015 letter, FDA provided feedback to you on September 2, 2015 and recommended that your firm submit a revised PS study plan addressing this feedback and the deficiencies identified in the Agency's February 13, 2015 letter as soon as possible. To date, FDA has received no response to this communication from your firm, Argo has not submitted a revised study

plan, and there has been a substantial lack of progress towards commencement of the 522 PS study required under the 522 Order.

Further, as stated within the 522 Order, a manufacturer must commence surveillance under section 522 of the Act not later than 15 months after the day on which an order is issued under section 522 (see section 522(b) of the Act). The 15-month time frame within which Argo's PS study plan must be approved and its study must be commenced closed on September 28, 2015.

Failure or refusal of a manufacturer to comply with requirements under section 522 of the Act, which includes requirements specified under 21 CFR Part 822, is a prohibited act under section 301(q)(1)(C) of the Act, 21 U.S.C. § 331(q)(1)(C). Further, failure or refusal to comply with a requirement under section 522 of the Act renders a device misbranded under section 502(t)(3) of the Act, 21 U.S.C. § 352(t)(3).

Argo Medical Technologies, Inc. has:

- failed to submit a revised PS study plan that adequately addresses the deficiencies described in FDA's September 29, 2014 letter, as well as those deficiencies described in FDA's February 13, 2015 letter (see 21 CFR 822.19);
- failed to design a PS study plan that answers the questions identified in the 522 Order (see 21 CFR 822.11);
- failed to have an approved PS study plan (see 21 CFR 822.20); and
- failed to commence surveillance under section 522 of the Act not later than 15 months after the day on which the 522 Order was issued (see section 522(b) of the Act).

Therefore, Argo has committed a prohibited act under section 301(q)(1)(C) of the Act by failing to comply with requirements under section 522 of the Act. Your firm's ReWalk device, authorized for marketing under de novo classification (K131798/DEN130034), is currently misbranded under section 502(t)(3) of the Act.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Please note that Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Within fifteen (15) calendar days from the date you receive this letter, please submit your firm's section 522 post-market surveillance study plan that addresses the deficiencies identified in the FDA letters dated September 29, 2014 and February 13, 2015. In addition, please notify this office in writing of the specific steps you have taken to correct the noted violations, as well as those actions performed to prevent recurrence for this order and future studies. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective actions cannot be completed within 15 calendar days, state the reason for the delay and the time within which the corrections will be completed.

66. The Company did not disclose to the investing public the multiple communications the Company had with the FDA from September 29, 2014 through September 30, 2015, indicating the

Company's failure to comply with FDA requirements for a postmarket surveillance study plan, required for continued marketing clearance for the ReWalk Personal.

67. Defendants did not disclose the FDA's September 30, 2015 Warning Letter, despite its obvious significance as a major risk factor for investors. Investors only learned of the FDA's September 30, 2015 Warning Letter on or about March 1, 2016, when the FDA published it on the FDA website.

68. The Company mentioned in its annual report for fiscal year 2015, filed on Form 10-K with the SEC on February 29, 2016 (the "2015 10-K"), only that ReWalk had received a single negative letter from the FDA. The 2015 10-K stated that in February 2016 the Company received a letter from the FDA "citing deficiencies in the protocol for the mandatory post-market study on our ReWalk Personal." 2015 10-K, at 23. The 2015 10-K made no mention of the prior FDA Warning Letter from September 30, 2015, or of any of the series of proceeding negative communications from the FDA. The 2015 10-K stated only the following:

> In February 2016, the FDA sent us a letter citing deficiencies in the protocol for the mandatory post-market study (conducted pursuant to a 522 order) on our ReWalk Personal 6.0 model and expressing the FDA's belief that we should submit a second premarket notification for the device. We intend to meet and discuss the February 2016 letter with the FDA. We expect that we may continue to sell our ReWalk Personal 6.0 model notwithstanding the outcome because of our good faith belief that our past 510(k) clearance covers the ReWalk Personal 6.0 and the public health significance of the device. Further, we currently expect that we will be able to address any deficiencies in our post-market study protocol. However, if the FDA were to decide instead to seek enforcement against us, the ReWalk Personal 6.0 model or any other product due to failure to satisfy this or any other 522 order, we could be prevented from selling the product in the United States, which could materially adversely affect our revenues and results of operations.

Defendants Conduct ReWalk's IPO Pursuant to the Registration Statement and Prospectus that Contained Materially Misleading Statements and/or Omitted Material Information

69. The Registration Statement and Prospectus were negligently prepared and, as a result, contained untrue statements of material facts and/or omitted to state other facts necessary to make the statements made not misleading and were not prepared in accordance with the rules and regulations governing the preparation of the Offering Documents.

70. In particular, the Registration Statement and Prospectus misrepresented the FDA marketing approval the Company received for the ReWalk Personal. Specifically, the Registration Statement and Prospectus misrepresented the conditional nature of the FDA direct *de novo* approval of the ReWalk Personal, which included extensive successful clinical and nonclinical testing, safety mitigation measures, and safety surveillance data and reporting requirements as required conditions for the ReWalk Personal to remain on market.

71. In the Registration Statement and Prospectus, the Company did not make clear to investors that the FDA's June 26, 2014 Letter had imposed upon the Company an extensive number of challenging specific requirements and identified numerous specific potential safety risks in the ReWalk Personal calling for mediation. Rather than presenting the FDA expedited and conditional direct *de novo* approval of the ReWalk Personal as what it was – a stage in an ongoing approval process dependent upon future clinical and nonclinical testing and the results of safety surveillance and reporting – the Company presented the ReWalk Personal as having been approved so long as it complied with government regulations.

72. In the first three pages of the Registration Statement and Prospectus, the Company described the FDA approval of the Company's direct *de novo* applications as, "our receipt of FDA clearance for ReWalk Personal," represented that the ReWalk Personal had "received FDA clearance to market it in the United States," and that, "*ReWalk Personal* is the first medical exoskeleton cleared by the FDA for personal use in the United States." While these statements are literally true, because of the uniquely conditional nature of the FDA *de novo* approval of the ReWalk Personal as detailed above, the proceeding statements claiming blanket clearance for marketing of the ReWalk Personal, were false and misleading. The Company had a long way to go to secure non-conditional clearance for market status, yet gave investors the impression that the Company was at the end of the FDA's approval process for marketing the ReWalk Personal, when the Company was not.

73. In the section of the Registration Statement and Prospectus devoted to "Risk Factors," the Company represented that instances of the ReWalk Personal causing injury to its users could "lead to safety recalls or safety alerts relating to the ReWalk (either voluntary or required by the FDA or similar governmental authorities in other countries)," without mentioning that the FDA's June 26,

2014 Letter made it clear that the FDA's conditional *de novo* approval was contingent on a lack of a significant number of safety mishaps with the product. By mentioning the cost of safety recalls, a far lesser danger to the long-term viability of the Company, but not the greater danger of failure to fulfill a major condition of the FDA *de novo* approval, the statement was false and misleading.

74. The single mention of the conditional nature of the FDA approval of the ReWalk Personal, appearing on page 22 of the Offering Documents, is false and misleading in that it artificially minimizes the number of issues raised, requirements imposed, conditions set, risk factors identified and mitigation steps required under the FDA's June 26, 2014 Letter. Notably, though the June 26, 2014 Letter, and its list of conditions to be met by the Company in order to continue marketing the ReWalk Personal, was the single most important document reflecting the long-term prospects of the Company – the Company did not include the FDA's June 26, 2014 Letter in its Registration Statement or Prospectus.

75. The statements made by the Company in the Registration Statement were materially false and misleading when made because the over 100-page long document contained only three generic references to "postmarket surveillance," and in this fashion misleadingly omitted meaningful communication of the very significant obligations the FDA had placed upon the Company going forward in order to retain clearance to market the ReWalk Personal. Instead, the Prospectus conveyed to a reasonable reader that the Company's product had been approved for marketing, limited only by compliance with ongoing government regulations.

76. On page 22, in the section entitled "Risks Related to Government Regulation," the Registration Statement states, in pertinent part:

> We are subject to extensive governmental regulations relating to the manufacturing, labeling and marketing of our products.
>
> Our medical products and manufacturing operations are subject to regulation by the FDA, the European Union, the Ministry of Health in Israel, and other governmental authorities both inside and outside of the United States. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, storage, installation, servicing, advertising, promoting, marketing, distribution, import, export and market surveillance of ReWalk.
>
> Our products are regulated as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FFDCA, as implemented and enforced by the FDA. Under the FFDCA, medical devices are classified into one of three classes—Class I,

> Class II or Class III—depending on the degree of risk associated with the medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device.
>
> In June 2014, the FDA granted our petition for "de novo" classification, which is a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to certain special controls. The special controls established in the de novo order include compliance with medical device consensus standards; performance of a postmarket surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain; non-clinical performance testing of the system's function and durability; a training program; and labeling related to device use and user training. In order for us to market ReWalk, we must comply with both general controls, including controls related to quality, facility registration, reporting of adverse events and labeling, and the special controls established for the device. Failure to comply with the general and special controls could lead to removal of ReWalk from the market, which would have a material adverse effect on our business.
>
> (Emphasis added.)

77. Under the "Risks" section of the Registration Statement there was no mention of the postmarket "special controls" the FDA placed upon the ReWalk Personal and on page 70 of the Registration Statement under "Government Regulations," the Company described only in general terms the direct *de novo* approval process. This description included a generic discussion of postmarketing "special controls" that might be imposed by the FDA upon a *de novo* product. However, the Company did not disclose the extensive postmarketing "special controls"which the FDA had placed upon the ReWalk Personal.

78. The statements made by the Company in the Registration Statement were materially misleading and/or omitted material information because: (i) they failed to disclose that the Company was unprepared and/or unable to comply with the FDA's "special controls" requirements, including the postmarket surveillance study of the ReWalk Personal that was approved for marketing in June 2014; and (ii) they failed to disclose that the Company was unprepared and/or unable to comply with the FDA's "special controls" requirements, including the postmarket clinical and non-clinical studies and surveillance study of ReWalk's product that was approved for premarketing in June 2014.

The Company Continues to Issue Materially Misleading Statements and/or Omit Material Information Following the IPO

79. Just as the Company had in the IPO issued false and misleading statements indicating that the ReWalk Peronal had been cleared for marketing by the FDA without disclosing their inability to comply with the FDA postmarketing "special conditions," defendants continued to conceal this fact after the IPO when the Company received letters from the FDA noting its noncompliance with the "special controls."

80. On March 26, 2015, the Company filed its annual report for a foreign issuer on Form 20-F/A for the fiscal year ended December 31, 2014 (the "2014 Annual Report"). The 2014 Annual Report was signed by defendant Jasinski, the Company's CEO. The 2014 Annual Report contained materially misleading statements and/or omitted materially information because the 2014 Annual Report stated only that the FDA had cleared the ReWalk Personal for marketing and made no mention of the existence or content of the following: (1) the FDA's September 29, 2014 letter (informing ReWalk that its proposed postmarket surveillance study plan lacked the basic required information which the FDA had demanded in its June 26, 2014 letter) and demanding a complete response within 30 days; (2) the FDA's November 5, 2014 letter (informing the Company that the Company had failed to timely respond to the FDA's September 29, 2014 letter); (3) the FDA's February 13, 2015 letter (informing the Company that the Company's November 6, 2014 proposed postmarket surveillance study lacked the basic required information which the FDA had demanded in its June 26, 2014 letter and demanding a complete response within 30 days; and, (4) the FDA's March 16, 2015 email informing the Company that the Company had failed to timely respond to the FDA's February 13, 2015 letter. In short, while informing the investing public that the Company had received a direct *de novo* approval in June 2014, the Company did not inform shareholders that the Company had failed to meet the explicit FDA conditions for converting the conditional direct *de novo* approval, to ongoing approval for marketing.

81. On October 1, 2015, the Company filed a registration statement and prospectus on Form F-3 with the SEC in connection with an additional offering of $100,000,000 of ordinary shares, warrants and/or debt securities offered by the Company and up to 3,614,808 ordinary shares offered

by a group of selling shareholders (the "Secondary Offering Documents"). The Secondary Offering Documents were signed by defendants Muir and Jasinski, as well as Secondary Offering Defendants Poduska and DiSanzo, both directors at the time of the Secondary Offering. The identities of the selling shareholders are not disclosed in the Secondary Offering Documents, but are identified as "those shareholders who have the right to include their securities in a registration or offering effected by us under the terms of our Amended and Restated Shareholders' Rights Agreement dated July 14, 2014." The parties to the Amended and Restated Shareholders' Rights Agreement, dated July 14, 2014, include, among others: affiliates of Israel Healthcare Ventures; affiliates of SCP Vitalife Partners; affiliates of Pontifax; and affiliates of Yaskawa.

82. The Secondary Offering Documents contained materially misleading statements and/or omitted material information. In particular, the Secondary Offering Documents, under a section entitled "Risk Factors," in which the reader was simply referred to the discussion of risk factors contained in the Company's annual report filed on Form 20-F/A on March 26, 2015 (the "2014 Annual Report"), failed to disclose the above-described FDA letters indicating that the Company was not in compliance with the primary condition of the FDA's direct *de novo* approval of the ReWalk Personal. Additionally, the Secondary Offering Documents contained materially misleading statements and/or omitted material information because they failed to disclose the Company's receipt of the FDA's June 24, 2015 letter notifying the Company via email that ReWalk's postmarket surveillance study did not comply with section 522 of the FD&C Act, and September 30, 2015 Warning Letter, detailing ReWalk's failure to propose, let alone conduct, an adequate postmarket surveillance study plan following the FDA's initial clearance and demand for such plan in June 2014.

83. The Company filed its annual report on Form 10-K on February 29, 2016 for the fiscal year ended December 31, 2015 (the "2015 10-K"). The 2015 10-K contained materially misleading statements and/or omitted material information because the 2015 10-K stated only that the Company had received a single negative letter from the FDA and that the single letter was received in February 2016 (2015 10-K, at 26), and made no mention of the prior September 30, 2015 Warning letter, or of any of the multiple negative communications from the FDA regarding the Company's postmarket surveillance study plan, which the FDA had issued from September 29, 2014 through September 30,

2015. The 2015 10-K was signed by the Individual Defendants and the Secondary Offering Defendants.

84. Also on February 29, 2016, the Company filed a registration statement and prospectus a Form S-3 in connection with an offering of $100,000,000 of ordinary shares, warrants and/or debt securities offered by the Company and up to 4,388,143 shares offered by a group of selling shareholders (the "February 29, 2016 Offering Documents"). The group of selling shareholders was the same group as described above in the Secondary Offering Documents. The February 29, 2016 Offering Documents contained materially misleading statements and/or omitted material information. In particular, under a section entitled "Risk Factors," in which the reader was simply referred to the discussion of risk factors contained in the 2015 10-K filed on the same date, the February 29, 2016 Offering Documents made no mention of the prior September 30, 2015 Warning letter, or of any of the multiple negative communications from the FDA regarding the Company's postmarket surveillance study plan, which the FDA had issued from September 29, 2014 through September 30, 2015. Accordingly, the February 29, 2016 Offering Documents contained materially misleading statements and/or omitted material information for the same reasons set forth regarding the 2015 10-K. The February 29, 2016 Offering Documents were signed by the Individual Defendants.

The Truth is Partially Revealed

85. On or about March 1, 2016, the FDA posted on its website the September 30, 2015 Warning Letter to ReWalk, which was picked up by the media.

86. The Company's year and a half ongoing failure to comply with FDA notifications regarding a compliant postmarket surveillance study plan was exposed by the FDA and the media on May 1, 2016. The following week, the Company for the first time disclosed to the public the Company's receipt of the September 30, 2016 Warning Letter in the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2016 (the "Q1 10-Q 2016"). The Q1 10-Q 2016 stated, in pertinent part:

The FDA has sent us letters suggesting a potential need for us to seek new premarket clearance for our ReWalk Personal 6.0 and stating that it may take regulatory action for deficiencies in our mandatory post-market surveillance study on the device.

On September 30, 2015, we received a warning letter (the "September 2015 Letter") from the Food and Drug Administration (the "FDA") citing deficiencies in our protocol for a post-market surveillance study of our ReWalk Personal and our failure to initiate a post-market study by the September 28, 2015 deadline. Between June 2014 and our receipt of the September 2015 Letter, we submitted our post-market study protocol to the FDA, amended the protocol in response to the FDA's subsequent request and proposed additional amendments to enhance the protocol after the FDA notified us that our subsequently-amended protocol was still deficient. While we responded to the FDA's requests throughout this period, we did not submit all of our responses on a timely basis. The September 2015 Letter warned that the FDA could take regulatory action against us for violations of Section 522 of the Federal Food, Drug and Cosmetic Act ("Section 522") based on the late post-market study and allegedly deficient protocol for that study. In February 2016, the FDA sent us an additional information request (the "February 2016 Letter") requesting additional changes to our post-market surveillance study protocol and asking that we comply within 30 days. In the February 2016 Letter, the FDA also expressed its belief that we should submit a new pre-market notification for our ReWalk device stemming from the FDA's review of what it considered to be changes to the device.

We held several discussions with the FDA, including an in-person meeting in March 2016, which based on our understanding of the conclusions reached by the FDA, resulted in the FDA narrowing its request for a new pre-market notification to an abbreviated, special application (the "special 510(k)"). This special 510(k) relates only to a computer included with the ReWalk device and is subject to an approximate 30-day review period, rather than the standard 90-day review period for pre-market applications. In late March 2016, the FDA confirmed that, based on these resolutions, we could continue to market our ReWalk device as long as we submit the special 510(k) and initiate the post-market study by June 1, 2016. Our special 510(k) submission was received by the FDA on April 11, 2016, at which time the FDA commenced its review of the special 510(k). Additionally, we have submitted a protocol for the post-market surveillance study that was approved by the FDA on May 5, 2016 and that we are required to commence within 30 days after that date. We expect to initiate our post-market surveillance study by the end of May 2016. The FDA also confirmed that, based on the public health significance of the ReWalk device, it did not view regulatory action against us for the late start in or deficient protocol for the post-market study as a priority for the agency, and that it expected to reassess the issues surrounding the pre-market notification and post-market study in June 2016. We have met all deadlines for submission of responses and have communicated regularly with the FDA after receiving each of the September 2015 Letter and the February 2016 Letter.

(Emphasis added.)

87. Critically, the Company admitted that ReWalk now expects to "be able to adhere fully to the FDA's timeline and to respond promptly to the FDA's requests based on significant additions in staffing aimed at addressing a need for greater internal clinical and regulatory resources." Thus, the

Company belatedly admitted that it previously was unable to comply with the FDA's special controls and, in particular, the postmarket surveillance requirement.

88. The Offering Documents, Secondary Offering Documents, 2015 10-K and February 29, 2016 Offering Documents contained materially misleading statements and/or failed to disclose material information necessary to make statements made not misleading. In particular, these documents failed to disclose that the Company was unprepared and unable to: (i) comply with the FDA's requirement pursuant to section 522 of the FD&C Act; (ii) provide the FDA with adequate information concerning its postmarket surveillance study; and (iii) conduct an adequate postmarket surveillance study. These documents failed to disclose that the Company was unable to fully comply with the FDA's special controls requirements in order for the Company to be able to continue marketing the ReWalk Personal. The failure to include such material information in the these documents renders the Offering Documents, Secondary Offering Documents, 2015 10-K and February 29, 2016 Offering Documents materially misleading.

89. After the truth was revealed in the FDA's Warning Letter, ReWalk's ordinary share price dropped by $2.58 per share, or approximately 22%, from $11.65 per share on February 25, 2016 to $9.07 per share on March 1, 2016. The Company's ordinary share price has continued to decline since the disclosure of the FDA Warning Letter and routinely trades around $2-3 per share currently.

NO SAFE HARBOR

90. ReWalk's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements were ineffective to shield those statements from liability.

91. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the false or misleading statements or material omissions pleaded with respect to the Securities Act claims. First, Section 27(A) of the Securities Act of 1933 provides that the statutory safeharbor "shall not apply to a forward-looking statement that is made in connection with an initial public offering." 15 U.S.C. § 772-2(b)(2)(D).

92. Second, none of the misstatements complained of herein were forward-looking statements. Rather, they were misstatements concerning current facts and conditions existing at the time the statements were made.

93. Third, to the extent that any statements may be construed as forward-looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements.

CLASS ACTION ALLEGATIONS

94. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the Class (as defined above). Excluded from the Class are defendants and their family members, directors and officers of ReWalk and their families and affiliates.

95. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of November 2, 2016, ReWalk had more than 16,334,008 ordinary shares outstanding, owned by hundreds or thousands of persons.

96. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:

a) Whether the Securities Act was violated by defendants;

b) Whether defendants omitted and/or misrepresented material facts;

c) Whether defendants' statements omitted material facts such that statements made, in light of the circumstances under which they were made, were rendered false and/or misleading;

d) Whether defendants negligently made false and misleading statements, or recklessly disregarded that their statements were false and misleading;

e) Whether the price of ReWalk's ordinary shares was artificially inflated; and

f) The extent of damage sustained by Class members and the appropriate measure of damages.

97. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from defendants' wrongful conduct.

98. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

99. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

FIRST CAUSE OF ACTION

For Violation of Section 11 of the 1933 Act Against All Defendants

100. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

101. This Cause of Action is brought pursuant to §11 of the 1933 Act, 15 U.S.C. §77k, on behalf of the Class, against all Defendants. Plaintiff disclaims all allegations of fraud.

102. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

103. ReWalk is the registrant for the IPO. The defendants named herein were responsible for the contents and dissemination of the Registration Statement.

104. As issuer of the ordinary shares, ReWalk is strictly liable to Plaintiff and the Class for the misstatements and omissions.

105. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

106. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated §11 of the 1933 Act.

107. Plaintiff acquired ReWalk ordinary shares pursuant and/or traceable to the Registration Statement for the IPO.

108. Plaintiff and the Class have sustained damages. The value of ReWalk's ordinary shares has declined substantially subsequent to and due to defendants' violations.

109. At the time of plaintiff's purchases of ReWalk ordinary shares, Plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts.

SECOND CAUSE OF ACTION

For Violation of Section 12(a)(2) of the 1933 Act Against

ReWalk, the Individual Defendants and the Underwriter Defendants

110. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

111. This Cause of Action is brought pursuant to §12(a)(2) of the 1933 Act, 15 U.S.C. §77l(a)(2), on behalf of the Class and against all defendants.

112. This Cause of Action does not involve fraud. Plaintiff does not allege that ReWalk, the Individual Defendants and/or the Underwriter Defendants had scienter or fraudulent intent, which are not elements of a §12(a)(2) claim.

113. ReWalk, the Individual Defendants and/or the Underwriter Defendants promoted and sold the Company's ordinary shares to Plaintiff, as well as other Class members through a defective Prospectus.

114. As stated above, the Prospectus contained false statements of material fact, and concealed and failed to disclose material facts as required by law. ReWalk, the Individual Defendants and/or the Underwriter Defendants failed in their duty owed Plaintiff and Class members who purchased ordinary shares to make a reasonable and diligent investigation into the statements in the Prospectus to make sure that the statements were true and that there was no omission to state a material fact that was required to be stated so that statements therein were not misleading. With reasonable care and exercise, ReWalk, the Individual Defendants and/or the Underwriter Defendants should have known of the misstatements and omissions described above.

115. Plaintiff did not know, nor in the exercise of reasonable diligence could have known, of the false information and omissions in the Offering Documents at the time Plaintiff acquired the ordinary shares.

116. Due to the conduct alleged, ReWalk, the Individual Defendants and/or the Underwriter Defendants violated §12(a)(2) of the 1933 Act. As a direct and proximate result of these violations, Plaintiff and other Class members purchased ordinary shares as a direct and proximate result of the above referenced violations. As such, Plaintiff and other Class members have suffered damages due

to their purchases. Plaintiffs and other Class members have the right to rescind and recover the consideration paid for their shares due to their ownership of ordinary shares issued pursuant to the Offering Documents.

117. As a result, Plaintiff and Class members hereby tender their ordinary shares to the defendants. Class members seek damages to the extent permitted by law resulting from the sale of their ordinary shares.

THIRD CAUSE OF ACTION

For Violation of Section 15 of the 1933 Act Against

ReWalk, the Individual Defendants and the Venture Capital Defendants

118. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

119. This Cause of Action is brought pursuant to §15 of the 1933 Act against ReWalk the Individual Defendants and the Venture Capital Defendants.

120. The Individual Defendants each were control persons of ReWalk by virtue of their positions as directors and/or senior officers of ReWalk. The Individual Defendants each had a series of direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of ReWalk. The Company controlled the Individual Defendants and all of ReWalk's employees.

121. Each of the Venture Capital Defendants controlled ReWalk by their voting and dispositive control over approximately 51% of ReWalk's outstanding voting shares, pre-IPO shareholder agreements, and by having designees on ReWalk's Board at the time of the IPO. The Individual Defendants each had a series of direct and/or indirect business and/or personal relationships with other directors and/or officers and/or major shareholders of ReWalk. The Venture Capital Defendants were control persons of ReWalk by virtue of their ownership of ReWalk ordinary shares and their rights to force ReWalk to register that stock for resale. ReWalk controlled the Individual Defendants and all of its employees.

122. The Venture Capital Defendants had a financial interest in taking the Company's ordinary shares public in order to increase the holding value and marketability of the Venture Capital

Defendants' investment in ReWalk. ReWalk, the Venture Capital Defendants and the Individual Defendants were each critical to effecting the IPO, based on their signing or authorization of the signing of the Registration Statement, by voting (including voting their shares) to execute the IPO, and by having otherwise directed through their authority the processes leading to execution of the IPO.

123. The Defendants each were culpable participants in the violations of §11 of the 1933 Act alleged in the Cause of Action above, based on their having signed or authorized the signing of the Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

A. Declaring this action to be a proper class action and certifying Plaintiff as Class representative;

B. Awarding compensatory damages in favor of the Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages, and;

E. Awarding such equitable/injunctive or other relief as the Court may deem just and proper;

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: January 24, 2017

REICH RADCLIFFE & HOOVER LLP

By: /s/ Adam T. Hoover
Adam T. Hoover